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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/473,619	12/29/1999	ROBERT SIMAN	02655/062002	1229

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1643

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/473,619

Applicant(s)

SIMAN ET AL.

Examiner

Christopher H. Yaen

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-11 and 13-45 is/are pending in the application.
- 4a) Of the above claim(s) 2-7,9-11 and 13-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/29/1999.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibits 1-3.

## **DETAILED ACTION**

***RE: Siman et al***

### ***Election/Restrictions***

1. Applicant's election with traverse of group I (claim 1) in the reply filed on 4/16/2001 is acknowledged. The traversal is on the ground(s) that the search for the different inventions would not be burdensome to search together. Specifically, applicant has requested at the very least that the inventions of groups I and II be search together because the invention involves subject matter of the same class. This is not found persuasive because the invention of group I is drawn to peptides (530/300), while the invention of group II is drawn to antibodies and a kit comprising said antibody (530/350+). Moreover, while the inventions of both group I and group II are polypeptides, in this instance the polypeptide of group I is a single chain molecule that is derived from an enzyme, whereas the polypeptide of group II encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group II are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group II is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Art Unit: 1643

In this case, the polypeptide of group I is a molecule which contains regions to which an antibody may bind, whereas the antibody of group II is defined in terms of its binding specificity to a small structure within SEQ ID NO: 1 and or 2. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group I and group II would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications (i.e. subclass). A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the peptide is necessary for a determination of novelty and unobviousness of the peptide. However, such a search is not required to identify the antibodies of group II. Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group II are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8 and 12 are canceled without prejudice or disclaimer.
3. Claims 1-7,9-11,13-45 are pending, claims 2-7,9-11, and 13-45 are withdrawn from further consideration as being drawn to non-elected subject matter.
4. Claim 1 is examined on the merits.

***Information Disclosure Statement***

5. The Information Disclosure Statement filed 12/29/1999 is acknowledged and considered. A signed copy of the IDS is attached hereto.

***Specification***

6. The disclosure is objected to because of the following informalities:
- a. The priority data must be updated to reflect the current status of application 08/967625 from which the instant application depends.
- Appropriate correction is required.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth a peptide sequence which consists of or comprises the sequence of SEQ ID No: 1 or 2, and therefore the written description is not commensurate in scope to the claims that read on a peptide sequence which consists of or comprises a sequence of SEQ ID No: 1 or 2 as claimed. The following *written description* rejection is set forth herein.

The claims recite "an amino acid sequence" of either SEQ ID No: 1 or 2 as part of the invention. This reads on a single amino acid found within the sequence of SEQ

Art Unit: 1643

ID No: 1 or 2. However, there does not appear to be an adequate written description in the specification as-filed that is representative of the single amino acid sequences derived from SEQ ID No: 1 or 2, which is encompassed by the claimed peptide sequences. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3<sup>rd</sup> column).

Applicant does not appear to have reduced to practice the broad genus of "an amino acid sequence" derived from either SEQ ID No: 1 or 2. Neither has Applicant provided a sufficient written description of any particular structure of "an amino acid sequence " derived from SEQ ID No: 1 or 2. "[A]n amino acid sequence" encompasses *any* amino acid sequence, as small as 2 amino acids, found within SEQ ID No: 1 or 2. Thus the genus of compounds encompassed by this phrase is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is also invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

It is noted that applicant may overcome this rejection by amending the claims to recite a peptide comprising "the amino acid sequence".

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1643

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Anderson DH *et al* (J. Bacteriol. 1989; 171(12):6468-6472). The claims are drawn to a substantially pure peptide comprising an amino acid sequence selected from the group consisting of SEQ ID No: 1 and 2. Anderson *et al* teach a “substantially pure” peptide comprising an amino acid sequence of SEQ ID No: 1 (see figure 5 and attached Sequence alignment-Exhibit 1A). Therefore the claim is anticipated.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dechert R *et al* (J Neurochem. 1989;53(4):1268-75). Dechert *et al* teach an isolated peptide comprising an amino acid sequence of SEQ ID No: 1. (see attached sequence alignment- exhibit 1B). Therefore the claim is anticipated.

11. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Yuan J *et al* (WO 95/00160). Yuan *et al* teach a peptide comprising an amino acid sequence of SEQ ID No: 2 (see figure 12A and attached sequence alignment-exhibit 3). It is noted that for the purposes of this rejection the phrase “an amino acid sequence” comprising SEQ ID No: 2 is read to the extent that any sequence of at least two amino acids in common would qualify as prior art.

### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 1643

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Talanian RV *et al* (US Patent 6,288,037, filed June 18, 1996). Talanian *et al* teach a peptide sequence which comprises an amino acid sequence of SEQ ID No: 1 (see SEQ ID No: 3 and also see attached sequence alignment- exhibit 2). Therefore the claim is anticipated.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1643

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1643  
January 3, 2006

  
**CHRISTOPHER YAEN**  
**PATENT EXAMINER**